UTILITY PATENT APPLICATION

TITLE:

APPARATUS, SYSTEMS, AND METHODS FOR WARMING MATERIALS

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INVENTORS:

James H. Layer (U.S. Citizen; Cooper City, FL)
Kenneth Solovay (U.S. Citizen; Weston, FL)
Thomas Jacobs (U.S. Citizen; Ft. Lauderdale, FL)

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Inventors: James H. Layer, Kenneth Solovay, and Thomas Jacobs

Cross-Reference to Related Applications

This application is a continuation-in-part of U.S. Application No. 09/909,407, filed July 19, 2001, now abandoned, which claims the benefit of U.S. Provisional Patent Application Serial No. 60/219,958, filed July 20, 2000, and U.S. Provisional Patent Application Serial No. 60/276,216, filed March 15, 2001. The disclosures of these applications are incorporated herein by reference.

Field of the Invention

The present invention relates to apparatus, systems, and methods for the warming of materials.

Background of the Invention

Commonly during the performance of surgical procedures utilizing sterile fields, solutions need to be used for irrigation of tissues and for other purposes. When irrigating solutions are used, or when irrigating solutions are applied to tissues over large surface areas, contact with a solution that is cooler than body temperature can lead to clinically important cooling of the tissues or of the entire patient and potential hypothermia. A supply of irrigating solutions at or warmer than body temperature is therefore generally kept available. Providing warmed solutions, however, requires attention from the nursing staff. Presently, sterile saline and other solutions for use in the operating room are warmed up and stored in heated cabinets. When additional warm solutions are needed, a nurse or technician must retrieve a fresh supply from the storage cabinet. The solution must then be sterilely poured into a receptacle on the sterile field, from which location it immediately begins to lose heat.

Receptacles available to hold surgical fluids are generally bowls or similar containers open to air and uninsulated. The typical receptacle for containing fluids

provides no means for maintaining the fluid's temperature. Therefore, even though initially warmed, the heated fluid rapidly cools after it has been poured. By the time the fluid is applied to the patient, it may be significantly cooler than body temperature. Application of those fluids to the patient may cause clinically important hypothermia. This hypothermia may have significant deleterious effects on patients including problems with blood clotting. In the pediatric patient population, hypothermia can be particularly hazardous to patients. To raise the temperature of a volume of fluid that has cooled, additional heated fluid may be added to the basin. This additional volume of fluid may be unnecessary for surgical purposes and is employed only to raise the mixture's temperature to a more suitable level. Similarly, the staff may not think of or have readily available newly warmed fluids, thereby exposing the patient to cool fluids and subsequent hypothermia. From the clinical standpoint, the additional fluid is unnecessary and may go to waste. Other methods besides fluid mixing would be desirable for keeping a volume of fluid warm on the sterile field.

Warming units have been devised for other applications where maintaining a sterile field is not an issue. U. S. Patent No. 4,996,405 and U. S. Patent No. 3,766,360 are examples of such devices. The surgical setting poses a distinct problem, however, in that any warmer adapted for residing on the sterile field must itself be sterile and remain sterile throughout the surgical procedure. The energy source for a warmer designed to reside on a sterile field must similarly not interfere with the ambient sterility of this workspace. There remains in the art, therefore, a need for a warming unit particularly adapted for functioning in a sterile surgical environment. Such a warming unit would desirably be in its outer aspect sterile or sterilizable. Such a warming unit would further be able to achieve a relatively constant temperature in a volume of fluid. Mechanisms for controlling temperature have been disclosed in other patents relating to devices suited for other, non-sterile applications, for example U. S. Patent Nos. 4,153,833, 4,900,161, and 4,962,297. Advantageously, a warming unit adapted for the surgical environment would be usable with conventional fluid receptacles. It would also be desirable to provide a warming unit efficiently fabricated from relatively inexpensive materials and adapted for use with disposable components.

No commonly available device exists that satisfactorily keeps a solution warm once it is on the sterile field.

Certain technologies are known in the art to use chemical means for providing local heat, for example U. S. Patent No. 4,077,390, U. S. Patent No. 4,872,442, U. S. Patent No. 5,791,334, U.S. Patent No. 6,116,231 and U. S. Patent No. 4,572,158. There remains a need in the art, however, for a warming apparatus particularly adapted to the needs of the surgical setting.

Summary

In an embodiment, an apparatus for generating heat comprises a rigid container within which a material to be warmed is contained, a chamber disposed about the container, and an activatable heating substance positioned within the chamber, which activatable heating substance when activated releases heat to warm the material within the container.

In an embodiment, the heating substance is a supercooled salt solution. In an embodiment, the apparatus further comprises an initiator which activates the heating substance. In an embodiment, the initiator comprises a plunger penetrably displaceable into the chamber to contact the activatable heating substance. In an embodiment, the chamber comprises a hole and a foil seal sealing the hole, and wherein the plunger is penetrably displaceable through the foil seal and the hole.

In an embodiment, the initiator comprises a plunger and a trigger coupled to the plunger, the plunger adjacent a hole into the chamber, and the hole sealed by a diaphragm, when the trigger is unpulled. In an embodiment, the plunger penetrates the diaphragm when the trigger is pulled, and the activatable heating substance is contacted to an ambient environment. In an embodiment, the plunger is hollow, and the ambient environment comprises a quantity of air inside the plunger.

In an embodiment, the activatable heating substance comprises calcium chloride, and the initiator comprises water. In an embodiment, the initiator comprises a plunger penetrably displaceable into the chamber and removably coupled to an activator. In an embodiment, the initiator comprises a spring flexibly mounted in an opening of the chamber. In an embodiment, the initiator comprises a disk flexibly mounted in an opening of the chamber.

In an embodiment, the initiator comprises a screw having a noninsulated proximal end and an electrically insulated distal end, which screw is disposed in a threaded hole into the chamber such that the proximal end does not contact the

activatable heating substance. In an embodiment, the screw is advanced through the threaded hole, whereby the proximal end contacts the activatable heating substance and activates the substance.

In an embodiment, the apparatus further comprises a lid removably coupled to the container. In an embodiment, the lid comprises a hinge and wherein a portion of the lid is hingedly rotatable.

In an embodiment, the apparatus further comprises an insulating sleeve disposed about the chamber. In an embodiment, the insulating sleeve comprises one of neoprene, styrofoam, or urethane.

In an embodiment, with activation, the activatable heating substance produces heat sufficient to warm the material within the container to a preselected temperature. In an embodiment, wherein with activation, the activatable heating substance produces heat sufficient to maintain the material above room temperature for at least about 2 hours and most preferably at least about 4 hours. In an embodiment, the activatable heating substance comprises about 1250 milliliters of supercooled sodium acetate solution having a concentration of about 17.68 molar, which substance upon activation produces heat sufficient to warm about 800 milliliters of material at about 68.5 degrees Fahrenheit to a temperature between 95 and 120 degrees Fahrenheit and maintain it between 95 and 120 degrees Fahrenheit for at least 4 hours. In an embodiment, wherein the activatable heating substance comprises about 400 milliliters of supercooled sodium acetate solution having a concentration of about 17.68 molar, which substance upon activation produces heat sufficient to maintain about 500 milliliters of material pre-warmed to about 98.6 degrees Fahrenheit at a temperature between 95 and 120 degrees Fahrenheit for at least 4 hours.

In an embodiment, the container comprises one of polypropylene, nylon, polyethylene, vinyl, stainless steel, and titanium. In an embodiment, the container comprises a spout. In an embodiment, the apparatus is sterilizable. In an embodiment the apparatus is designed to work with existing surgical fluid bowls.

In an embodiment, the heating substance has a first state prior to activating and a second state after activating. In an embodiment, the heating substance is restored to the first state after activation and may be activated again.

In an embodiment, a warming container comprises an inner wall and an outer wall, the inner wall defining an inner chamber to receive an article to be warmed therein, the outer wall and inner wall defining an outer chamber, the outer chamber being airtight,

the inner wall separating the outer chamber from the inner chamber and preventing communication between the chambers; a supercooled aqueous salt solution, disposed within and at least partly filling the outer chamber; and an initiator associated with the warming container for selectively activating the supercooled aqueous salt solution to cause the solution to undergo an exothermic crystallization.

In an embodiment, a warming container comprises a bowl, a sleeve disposed about the bowl, the bowl and sleeve defining a chamber therebetween, and a bag containing an activatable heating substance disposed within the chamber.

In an embodiment, a system for warming surgical fluids comprises a power source; a sterile enclosure for the power source; a resistive heater powered by and operably connected to the power source, the resistive heater being capable of being rendered sterile prior to its operable connection to the power source and further capable of remaining sterile after being operably connected to the power source; and a bowl holder dimensionally adapted for stably holding a surgical bowl and capable of transferring heat produced by the resistive heater to surgical fluid contained within the surgical bowl.

In an embodiment, the power source comprises a rechargeable battery. In an embodiment, the sterile enclosure is disposable. In an embodiment, the resistive heater surrounds a portion of the surgical bowl. In an embodiment, the system further comprises a temperature controller for regulating the heat produced by the resistive heater. In an embodiment, the system further comprises a temperature feedback system having a temperature sensor that senses the temperature of the fluid within the surgical bowl and a temperature signaler that signals the temperature controller to regulate the heat produced by the resistive heater so as to achieve a pre-selected temperature within the fluid.

In an embodiment, a method for warming a material comprises providing an apparatus for generating heat, comprising a rigid container and an activatable heating substance disposed about the container; positioning the material to be warmed within the container; and activating the heating substance.

In an embodiment, a method for warming a material comprises providing an apparatus for generating heat, comprising a rigid container, placing an activatable heating substance around the container; positioning the material to be warmed within the container; and activating the heating substance.

In an embodiment, a method for warming a material comprises providing an apparatus for generating heat, comprising a rigid container, an activatable heating substance disposed about the container, and an initiator to activate the activatable heating substance; positioning the material to be warmed within the container; and activating the initiator.

In an embodiment, the heating substance has a first state prior to activating and a second state after activating. In an embodiment, the method further comprises restoring the heating substance to the first state.

Brief Description of the Figures

The following figures depict certain illustrative embodiments in which like reference numerals refer to like elements. These depicted embodiments are to be understood as merely illustrative of embodiments and not limiting in any way.

FIG. 1 depicts a perspective view of an embodiment of a surgical solution warmer system.

FIG. 2A depicts a top view of an embodiment of a fluid warmer system.

FIG. 2B depicts a side view of an embodiment of a fluid warmer system.

FIG. 2C depicts a front view of an embodiment of a fluid warmer system.

FIG. 3 depicts a side view of another embodiment of a fluid warmer system.

FIG. 4 depicts a partial cross-section view of an embodiment of a fluid warmer system.

FIG. 6 depicts a cross-section view of an embodiment of a surgical solution warmer system.

FIG. 7 depicts in partial cross-section an embodiment of an activation assembly.

FIG. 8 depicts a cross sectional view of another embodiment of a solution warmer system.

FIG. 9 provides a perspective view of embodiment of a solution warmer system and air activation mechanism.

FIG. 10 depicts the solution warmer system and a spring activation mechanism.

FIG. 11 depicts the solution warmer system and a disk activation mechanism.

FIG. 11A depicts the solution warmer system and a screw activation mechanism.

FIG. 11B depicts the solution warmer system and a screw activation mechanism in the activated mode.

FIG. 12 depicts a solution warmer having a bag containing activatable heating substance.

FIG. 13 is a graph showing a heating profile of a warmer containing prewarmed fluid.

FIG. 14 is a graph showing a heating profile of a warmer containing room temperature fluid.

FIG. 15 is an exploded perspective view of an alternate embodiment of the surgical solution warmer.

FIG. 16 is a partially exploded perspective view of the heating actuation mechanism of the embodiment of FIG. 15.

Detailed Description

1. General

Any device being considered for use in the operating room, cardiac catheterization lab, interventional radiology suite, or other sterile settings readily apparent to one of skill in the art should provide certain features so that it can be safely used in the surgical setting. First, a warmer being kept on the sterile field must not interfere with the sterility of the sterile field. Next, a warmer must be electrically safe in the presence of flammable anesthetics and other gases. In addition, a warmer should warm fluids to a preselected temperature range so that the fluids are not too hot or too cool to be safely applied to the patient. Furthermore, the container for the fluids being kept warm should desirably either be disposable or easily sterilizable. Additionally, because the tables used for holding instruments and other apparatus used in surgery are moved around during the prep process and sometimes during the surgery, it is preferred that the warmer be completely mobile without the need for further set up or prep each time it is moved. In some instances it is desirable to configure the warmer for use with existing hospital surgical fluid bowls.

2. Definition

As used herein, the term "activatable heating substance" includes any substance that responds to an initiator or an initiating stimulus by producing heat. Examples of such substances include supercooled salt solutions and any compounds capable of undergoing exothermic chemical or physical changes. Initiating stimuli include application of any form of energy, including chemical, mechanical, thermal, solar, electromagnetic, ionizing radiation, and any other form of energy known to one of skill in the art.

3. Embodiments

In one embodiment, depicted in FIG. 1, a fluid warmer system 10 is adapted for keeping solutions warm on a sterile field. FIG. 1 illustrates a bowl 222 that may contain fluids, the bowl being positioned upon a warming mechanism. The warming mechanism may include a resistive heater 214 upon which or within which the bowl 222 may be seated or positioned. A resistive heater 214 may be constructed to match the size or shape of the bowl 222. As used herein, the bowl 222 may be any type of receptacle adapted for containing surgical fluids. For example, a metal solution bowl commonly available in the operating suite may be used. Similarly, a metal pitcher may be used as a bowl 222 to contain fluids within the solution warmer system 10. Customized bowls may be devised and included as part of the solution warmer system 10. While standard plastic irrigation bowls may not be suitable because they will not tolerate prolonged elevated temperatures, it will be apparent to practitioners in the art that alternative materials for bowl construction may be employed satisfactorily within the scope of the present invention. In the depicted embodiment, there is a depression in the resistive heater plate 214 that provides a bowl holder 228 for the bowl 222. Other types of bowl holders 228 can also be employed. For example, a latch may be provided that clips onto a rim or groove in the bowl 222. Or a spring loaded button may be configured to snap into an indentation in the bowl. Other securing arrangements may also be constructed. The resistive heater 214 may be positioned at the bottom of the bowl 222 as illustrated in FIG. 1. Alternatively, a resistive heater 214 may be constructed that surrounds the bowl 222 entirely or partially. In such an embodiment, the shaping of the resistive heater 214 that holds the bowl 222 is understood to be a bowl holder 228, as the term is used in this application. In the depicted embodiment, a temperature sensor 224 is shown as part of

the warming mechanism. The temperature sensor 224 functions to keep the temperature of the resistive heater 214 at an appropriate level. The temperature sensor 224 may include a feedback circuit or any other arrangement familiar to skilled artisans for regulating temperatures. In the depicted embodiment, a temperature controller 220 is illustrated that performs the necessary temperature adjustments in response to signals from the temperature sensor 224. FIG. 1 shows an enclosure 212 positioned to cover the internal elements of the solution warmer system 10. These internal elements include a battery 218 and the temperature controller 220. The enclosure 212 may be provided as a sterile or sterilizable box-like structure into which the assembled internal elements may be placed. In certain embodiments, the enclosure 212 may be disposable and intended for single use. The enclosure 212 is adapted for becoming and remaining sterile on the back table in the operating room. Similarly, the warming mechanism and the bowl 222 are adapted for becoming and remaining sterile. The construction of the fluid warmer system 10 provides, therefore, an entirely sterile device that should pose no risk to the integrity of the sterile field.

Figs. 2A, 2B and 2C show, respectively, a top view, a side view and a front view of an embodiment of the present invention. FIG. 2A depicts the top of the fluid warmer system without a bowl in place. The resistive heater 214 as shown here is a square plate with the temperature sensor 224 centered therein. As mentioned previously, other shapes of the resistive heater 214 may be utilized in the present invention. Similarly, other positionings of the temperature sensor 224 are consistent with the present invention. FIG. 2B shows a side view of the device, with its contents made visible. Illustrative dimensions are marked on the figure. In this figure, a battery charger 230 is shown along with a sealed lead acid battery 218 and a temperature controller 220. The battery charger 230 may run from a standard alternating current as would be found in the operating room, permitting the lead acid battery 218 to be charged during the procedure as necessary. In other embodiments of the present invention, there may not be a battery charger 230 present in the device. In these embodiments, the fluid warmer might be entirely powered by non-rechargeable batteries. Yet other embodiments might rely upon an external source of power instead of batteries. FIG. 2C shows a front view of the warming device with its contents made visible, wherein the battery 218, the temperature controller 220 and the battery charger 230 are seen, all enclosed within the enclosure 212. Those elements that singly or in combination provide power to heat the resistive heater 214 may be termed the power source. An indicator may be provided on the

surface of the enclosure 212 to show battery life, the charging status of the battery, or the use of an external power source.

FIG. 3 shows one possible configuration of the enclosure 212. In the depicted embodiment, the enclosure is shown to have a lid 240 which may be opened and closed to admit the internal elements of the device. As has been previously described, the enclosure 212 is adapted for holding such internal elements as a battery, a battery charger, and a temperature controller. The lid 240 shown in FIG. 3 opens at a hinged junction 242 and closes with a latch 244 at the end opposite the hinged joint 242. Any type of easily operated latch 244 would be suitable. The lid 240 opens sufficiently that the internal elements can be placed within the enclosure 212 without contaminating the external surface of the sterile enclosure 212. In the depicted embodiment, attachment pegs 248 may be seen which interface with the internal elements of the device and also interface with the resistive heater 214. As shown in this figure, the attachment pegs 248 are dimensionally adapted for fitting into a corresponding set of attachment slots 250.

Energy to power the resistive heater 214 may flow from the internal elements through the attachment pegs 248, thereby to pass unimpeded through the sterile enclosure 212. Other opening mechanisms for the enclosure 212 may be substituted for the embodiment depicted here. For example, a specially constructed battery and related apparatus may be inserted into a slot provided in the enclosure 212 using a tool shaped to fit into the slot on a distal end and shaped to be held on its proximal end by a circulating nurse in the operating room on its proximal end. In another embodiment, a hinge door may be provided on a lateral aspect of the enclosure through which a battery could be inserted into the device. A tool could be provided with a distal sterile end that could releasably engage the hinge door, permitting the circulating nurse to open and close it. The proximal end of the tool, available for the nurse to hold, could allow the nurse to open and close the door and further could there be releasing mechanism so that the tool could be disengaged from the hinge door once it is secured.

FIG. 4 depicts yet another embodiment of the present invention, showing a bowl 222 surrounded by a resistive heater 214 so that fluids in the bowl are heated on all sides. A lid 262 is also shown as a useful option for keeping the heated fluids warm. The resistive heater 214 is shown schematically in relation to the internal elements 260 of the warming system 10. It is understood that the internal elements 260 may not reside below the resistive heater 214, but rather may be positioned in a convenient place that allows

them to provide energy to the resistive heater 214 and also allows them to be inserted into the sterile or sterilizable enclosure 212.

In certain embodiments, sterility may be ensured by providing a disposable sterile drape adapted for enclosing the enclosure surrounding the internal elements. In these embodiments, the sterile drape comprises a sterile enclosure for the power source. An alternative to integrating the heater into the warming plate is to integrate the heater coil into the disposable drape. A variety of shapes for the heating element may also be envisioned. A representative shape of heating coils or heating etchings is attached as FIG. 5, although a wide variety of other shape arrangements can be used, as will be appreciated by practitioners of ordinary skill.

FIG. 6 depicts an embodiment of a surgical solution warmer system 10 according to the present invention. The figure provides a cross sectional view of the warmer system 10 having a fluid receptacle 12 with a receptacle wall 14. The receptacle wall 14 is in direct contact with a chamber 20 which may be filled with a chemical solution or activatable heating substance that, upon activation, generates heat energy. The receptacle wall 14 may be made of any material that will transmit heat to a solution placed within the fluid receptacle 12 and that will tolerate the heat generated by activated heating substance. In an embodiment, polypropylene may be used to form the fluid receptacle 12. The receptacle 12 may also be formed from other materials, such as nylon, polyethylene, vinyl, stainless steel, and titanium, and other materials may readily be envisioned by practitioners of ordinary skill in the art. In the depicted embodiment, fluid may be poured into the fluid receptacle 12 through a hinged lid 38. The hinge 40 shown in FIG. 6 is placed in the mid portion of the lid 38. Other hinged arrangements and other opening and closing mechanisms for the lid may be provided in other embodiments of the present invention.

In the depicted embodiment, the chamber 20 for holding the heating substance is contained between the receptacle wall 14 and an outer wall 18. An insulator or sleeve 22 may be provided to retain the heat generated by the activated heating substance within the warmer system 10. In one embodiment, the fluid receptacle 12 could be made to contain one to two liters of solution and may keep that solution at body temperature for between about two and five hours, depending on environmental conditions and container design.

In an embodiment, a warmer system according to the present invention may use the technology of supercooled fluids to produce heat. In one embodiment, a food grade salt such as sodium acetate may be instilled into the chamber 20 as the activatable heating substance. This salt freezes (crystallizes) at 130 degrees Fahrenheit and is supercooled while contained within the chamber. Supercooling may be achieved by melting all crystals (accomplished, e.g., by immersing in a sufficiently hot liquid, oven, autoclave, or microwave energy source) and allowing the solution to cool. The supercooled liquid may be made to crystallize by introducing a metallic nidus for crystallization. As the supercooled liquid crystallizes, its temperature increases to the freezing point of 130 degrees Fahrenheit. This heat may then be conducted across the receptacle wall 14 to heat the fluid contained within the fluid receptacle 12.

Other suitable supercooled solutions include lead acetate, calcium nitrate tetrahydrate, sodium pyrophosphate, sodium thiosulfate, and trimethylol ethane hydrate. Chemical heating from within the chamber 20 may also be achieved by using other agents, for example calcium chloride that can be activated by water. It is particularly advantageous to provide heating substances that can be reused simply by autoclaving or otherwise heating the container to reactivate them.

FIG. 7 shows one embodiment of an activation assembly 24 adaptable for use in the present invention. This figure shows a cross-section of a wall of the solution warmer system 10. The chamber 20 is shown, wherein heating substance may be placed ready for activation. The activation assembly 24 as shown here uses a plunger tip 32 as the nidus for crystallizing the supercooled liquid contained within the chamber 20. According to the illustrated embodiment, pressure may be exerted upon the plunger plate 28 to propel the plunger tip 32 through an aperture 30 that has been previously sealed. As the plunger tip 32 is urged into the aperture 30, it breaks the seal 31. The aperture 30 is dimensionally adapted so that it will receive the plunger rod 34 in an airtight fit. The fit of the plunger rod 34 within the aperture 30 effectively seals the chamber 20 so that none of the heating substance can escape. Once the plunger tip 32 comes into contact with the heating substance, crystallization will take place, with the production of heat as previously described.

In the depicted embodiment, the plunger system may be removable so that a hot solution of sodium acetate or similar heating substance can be installed into the chamber 20 through the aperture 30, following which the aperture 30 may be sealed. The plunger

system may be then reinstalled and positioned so that it can be activated with finger pressure to penetrate the sealed aperture 30 and thus contact the heating substance to initiate crystallization. Other systems using similar plunger type mechanisms may also be designed in keeping with the spirit of this invention. A variety of plunger materials and surface finishes can be envisioned that may facilitate piercing the sealed aperture 30 or that may more advantageously activate the heating solution.

The plunger apparatus or similar activation assembly 24 may be positioned on any surface of the solution warmer system 10. Although the activation assembly 24 is shown in this figure as if situated on the top of the system 10, it can just as readily be positioned on the side or on the bottom to permit easy access. Although the depicted system 10 as shown in these figures illustrates a chamber 20 into which a heating substance may be directly poured, it is understood that a heating substance may be installed in the warmer system pre-contained within a bag, a box or some other container that could be penetrated by the activation assembly 24 in order to produce heat.

FIG. 8 depicts an embodiment of a solution warmer 10 configured as a pourable pitcher 42. In the depicted embodiment, fluid is retained within a fluid reservoir 48, having been poured through a spout 58. Surrounding the fluid reservoir is an inner wall 50 adjacent to which activatable heating substance 44 such as sodium acetate crystals integrated in the container wall is directly applied. Surrounding the heating substance 44 is an outer wall 52 that also serves an insulating function. This embodiment features a handle 54 that would allow fluids within the fluid reservoir 48 to be easily poured through the spout 58 as needed. A variety of lids (not shown), hinged, press fit, screwtop, latched, or otherwise, may be constructed appropriately for the dimensions of the spout 58. In the illustrated embodiment, the warming capability is integrated directly into the pouring container, allowing freedom to dispense solutions directly and easily.

The pourable pitcher 42 shown in FIG. 8 can be made disposable with cheap, injection-molded materials, or it can be made reusable by employing more durable plastics or metal materials. Materials may include nylons, polyethylene, vinyl, and other plastics or ceramics familiar to skilled artisans, or may include metals such as stainless steel, titanium or others. As with the previously depicted embodiment, a variety of activation mechanisms are available. For example, activation can be by a metal disk that is brought into contact with the heating substance 44. Or, for example, a plunger

mechanism may be used. Triggers may be placed on the handle 54 that, upon depression, urged the activating element into the heating substance.

FIG. 9 depicts a solution warmer 10 according to the present invention configured as a pourable pitcher 42 featuring an air activation mechanism 60 attached to the handle 54. It has been demonstrated that exposure to air has the ability to initiate crystallization of supercooled sodium acetate solution and other activatable heating substances. The air activation mechanism 60 depicted herein is predicated upon this observation. In this figure, a rubber diaphragm 64 is shown covering an opening (not shown) in the outer wall 52. The trigger arm 62, when pulled, urges forward a hollow plunger 68 that penetrates the rubber diaphragm 64. This allows the inflow of a controlled amount of air, based upon the dimensions of the hollow interior of the hollow plunger 68. This embodiment also permits filling or refilling of the heating substance through the outer wall 52, with the opening used for filling being coverable by the rubber diaphragm 64. In the depicted embodiment, controlled activation of the heating substance is available without use of a metal disk or rod that might migrate around within the container or need to be physically deform. A variety of trigger in plunger mechanisms may be used to allow controlled exposure of air into the heating substance. Other containers, such as PVC bags containing sodium acetate can also be activated by air by using other systems, such as a manual open and close valve or check valve (one-way valve) to let air into the bag. This embodiment is illustrated with a hinged lid 70; as will be appreciated by skilled practitioners, a variety of lids and stoppers may be substituted.

FIG. 10 shows another embodiment of an activation assembly adapted for use in the present invention. This figure shows a cross section of a wall of the solution warmer system 10. The chamber 20 is shown wherein an activatable heating substance may be placed ready for activation. An initiator 100 includes a metal spring 102 as the nidus for crystallizing the activatable heating substance contained within the chamber 20. The spring 102 is stretched across an opening of the chamber 20 and the ends of the spring suitably anchored. A flexible membrane 104 is applied across the opening in the chamber 20, enclosing the spring 102 such that the chamber 20 is sealed. According to the illustrated embodiment, pressure may be exerted on spring 102 through the flexible membrane 104 causing the spring 102 to flex. The flexing of the spring 102 initiates crystallization in the activatable heating substance.

FIG. 11 shows another embodiment of an activation assembly adapted for use in the present invention. This figure shows a cross section of a wall of the solution warmer system 10. The chamber 20 is shown wherein activatable heating substance may be placed ready for activation. An initiator 100 includes a metal disc 108 as the nidus for crystallizing the activatable heating substance contained within the chamber 20. The disc 108 is disposed in an opening in the chamber 20 and the edge of the disc suitably anchored. A flexible membrane 104 is applied across the opening in the chamber 20 such that the chamber 20 is sealed. According to the illustrated embodiment, pressure may be exerted on the disc 108 through the flexible membrane 104, causing the disc 108 to flex. The flexing of the disc 108 initiates crystallization in the activatable heating substance.

FIG. 11A shows another embodiment of an activation assembly adapted for use in the present invention. This figure shows a cross section of a wall of the solution warmer system 10. The chamber 20 is shown wherein activatable heating substance may be placed ready for activation. A screw 110 penetrates the chamber 20 through a threaded hole. The screw has a noninsulated proximal end 112 and an electrically insulated distal end 114. The proximal end 112 may have bare metal, which provides the nidus for crystallizing the activatable heating substance contained within the chamber 20. The screw 110 is partially threaded into a hole in the chamber 20. The threads can be molded into the wall of the chamber 20 or a standard nut can be spin welded or otherwise mounted onto the chamber wall.

The screw 110 may be a metal screw, comprising preferably aluminum or stainless steel. The electrically insulating material disposed on the distal end 114 may be any suitable electrically insulating material, and is preferably a polymer coating on the distal end 114. The screw 110 and female threads are dimensioned to provide sufficient interference to make an airtight hermetic seal. There may be optionally applied a coating or an additional section of a different material to the female threads to ensure the seal is completely airtight during all shipping and sterilization processes. Alternatively, the screw can be non-metal and contain an insert or coating of a suitable activating material. An example of such embodiment is a plastic screw with a metal insert capable of activating the warmer when the insert contacts the solution. During manufacture, the screw 110 is partially screwed into the chamber wall such that only the electrically insulated distal end protrudes into the chamber and contacts the activatable heating

substance. This screw insertion may take place while the activatable heating substance is still well above its melt temperature.

With reference to FIG. 11B, the solution warmer may be activated by turning the screw 110, thereby causing the proximal end 112 of the screw 110 to enter the chamber 20. Once the proximal end 112 enters the chamber 20 and contacts the activatable heating substance, the surface energy associated with the metal provides the energy of crystallization required to begin the desired exothermic reaction.

FIG. 12 shows yet another embodiment of a surgical fluid warmer. In this embodiment a bag 118 containing activatable heating substance is provided. A bowl fits within the sleeve 22 of the warmer 10, thereby defining a chamber 20. A bag 118 containing an activatable heating substance occupies the chamber 20. When heating is desired, the activatable heating substance is activated inside the bag 118 in any manner described herein or in, e.g., U.S. Patents Nos. 5,791,334, 5,736,110, 5,058,563, 5,056,589, 4,899,727, 4,872,442, 4,860,729, 4,829,980, 4,587,950, 4,572,158, and 4,077,390, the disclosures of which are incorporated herein by reference. The bowl is placed on top of the bag 118. Surgical fluid may be introduced into the bowl at any time. In this embodiment the bag 118 may be replaced during a procedure to prolong the heating action of the warmer.

Although the apparatus, systems and methods described herein may be adapted for deployment in a sterile field, they may also be deployed in a nonsterile field. They may also be maintained in a nonsterile field that was formerly sterile.

Any of the above embodiments may be further insulated to prolong heating capacity by the addition of an insulating sleeve 22 around the fluid warmer. Such insulating sleeve 22 can be made from any suitable insulating materials including but not limited to neoprene, styrofoam or urethane. Additionally, insulation can be incorporated into the fluid warmer body or an air space provided for insulation.

In an embodiment, supercooled sodium acetate is used as the activatable heating substance. When activated, the supercooled sodium acetate is an exothermic energy source. In an embodiment, the concentration of the sodium acetate solution is between about 10 to about 20 molar, preferably between about 17 and about 18 molar, more preferably about 17.68 molar. As will be appreciated by one of skill in the art, molarity of the solution can be adjusted to vary the heating profile.

Example 1

A surgical warmer as disclosed above was constructed containing 400 ml of supercooled 17.68 molar sodium acetate solution. 500 ml of water pre-warmed to 98.6 degrees Fahrenheit was added to the container and the activatable heating substance activated. The external walls and lid of the warmer were insulated with a one-quarter inch insulating neoprene sleeve. The warmer achieved a heating profile as shown in FIG. 13. The warmer maintained the solution at a temperature equal to or greater than 100 degrees Fahrenheit for a duration equal to or greater than about 4 hours.

Example 2

A surgical warmer was constructed as disclosed above containing 1250 ml of supercooled 17.68 molar sodium acetate solution. 800 ml of water at 68.5 degrees Fahrenheit was added to the container and the activatable heating substance activated. The external walls and lid of the warmer were insulated with a one-quarter inch insulating neoprene sleeve. The warmer achieved a heating profile as shown in FIG. 14. The warmer warmed the solution to a temperature equal to or grater than 100 degrees Fahrenheit in a time period less than 1 hour and maintained the solution at a temperature equal to or greater than 100 degrees Fahrenheit for a duration equal to or greater than about 4 hours.

Referring to FIG. 15, an alternate embodiment for a surgical solution warmer is illustrated. Outer housing 200 holds activatable heating substance container 202 and inner housing 204. Insulation (not shown) may be disposed between outer housing 200 and inner housing 204. Activatable heating substance container 202, or heating "puck" 202, as fully explained hereinbelow, holds the activatable heating substance as described elsewhere hereinabove. Container 206, which holds a fluid to be maintained in a warm state, is inserted and retained in inner housing 204. Container 206 can be made in the format of a common pitcher, or other suitable form. Heat from heating puck 202 heats the fluid within container 206. Lid 208, which may include an insulator 210, may attach to outer housing 200, and further insulates container 206 from heat loss. As stated hereinabove, the solution warmer members may be made of various materials, including moldable plastic, metal, with all or some portions disposable, or sterilizeable. For example, heating puck 202 could be a metal, such as stainless steel, which can be

sterilized, and container 206 could be disposable and intended for a single use. Inner housing 204 can be configured to be removable from outer housing 228, to permit easy access to heating puck 226 for removal. Heating puck 226 could then be independently sterilized and the activatable heating substance can be restored to it pre-activated state

Referring to FIG. 16, heating puck 202 can include a first reservoir half 212 and a second reservoir half 214, which may threaded together with a suitable seal, such as o-ring 215, to form a sealed reservoir 216 to hold the activatable heating substance. The activation assembly to begin the exothermic reaction of the activatable heating substance is made-up of magnet 218 affixed to the distal end of spring 220. In this embodiment, heating puck 202 is made of stainless steel or other nonferrous material. Spring 220 is fixed at the proximal end by base member 222. By moving a ferrous metal or other magnetically attractive member, preferably disposed outside the reservoir 216 but in the vicinity of magnet 218, spring 220 can be made to flex or deflect as illustrated by arrow 224. The deflection of spring 220 begins the activation of the activatable heating substance as previously described hereinabove. Referring back to FIG. 15, a ferrous metal member can be disposed in the bottom of container 206 (not shown) so that rotation of container 206 in relation to heating puck 202 will move magnet 218 causing spring 220 to flex or rotate about base member 222 as shown by arrow 224 in FIG. 16. Alternately, heating puck 202 my contain arm 226, which fits into an opening 228 in the base of outer housing 200. Arm 226 can be used to rotate heating puck 202 in relation to container 206, which contains a ferrous metal member in its bottom.

Alternately, magnet 218 can be positioned on container 206 and a ferrous or magnetically attractive member disposed at the distal end of spring 220.

Other equivalent mechanisms are envisioned for relative motion between a magnetically attractive member in the vicinity of heating puck 202 and magnet 218 in order to attract and move magnet 218 in relation to fixed base member 222, which results in bending of spring 220 and the initiation of the exothermic reaction to cause heating effect.

It will be understood that embodiments of the invention described above are illustrative of some of the applications and principles of the present invention. Various modifications may be made by those skilled in the art without departing from the spirit and scope of the invention. Furthermore, although the present invention has been

illustrated by reference to embodiments usable in a medical setting, the solution warmer system and activation assembly are adaptable to a variety of non-medical purposes, as will be evident to those of ordinary skill in the art. For example, a pourable container as described above could be used with some modification to keep other liquids warm. A person of ordinary skill in the art could adapt the systems described herein to produce, for example, an insulated container to incubate a beverage. Accordingly, the invention is not to be limited to the illustrated embodiments provided above, but is to be understood by the claims set forth below, which are to be interpreted as broadly as allowed by law.